



September 8, 2026

Dr. Kris Thayer
 Director
 Office of Environmental Health
 Hazard Assessment (OEHHA)
 1001 I Street
 Sacramento, CA 95814

Re: 2026 Pre-Rulemaking Discussion Draft – Topic 4 – Naturally Occurring

Dear Dr. Thayer:

The coalition of food growers and producers identified as signatories to this letter (the “Food Coalition”) appreciates the opportunity to provide comments on a possible change to the naturally occurring regulation that implements Proposition 65, section 25501(a)(3). OEHHA shared this possible change as a “for discussion purposes only” draft (the “Discussion Draft”). Our comments below illustrate our considerable concerns with the Discussion Draft and the need for additional discussion prior to OEHHA taking any further action.

The Food Coalition includes a broad range of food growers and producers. California food and beverage processing supports more than 760,000 jobs, generates about \$82 billion in value added and \$221 billion in economic output, and contributes roughly \$8.2 billion in state and local taxes.

The Discussion Draft's change to section 25501(a)(3), identified as Topic 4, does not achieve its claimed purpose of "clarifying when a chemical is naturally occurring in a product." The current regulation is clear. The Final Statement of Reasons ("FSR") for section 25501 describes the clear, evident effect of the regulation:

"[I]t is evident from the regulation as a whole that once a chemical is exempt as a naturally occurring chemical in food, the exempt status of that particular chemical will 'carry over' to any other food to which it is added." FSR at 9 (emphasis added).

This clear, logical and reasonable statement of the effect of section 25501 should be maintained, it needs no regulatory clarification. This passage makes clear that "adding" a chemical that itself is a food to another food does not change the natural creation of the chemical and thus does not cause the "carry over" food to create a chemical "exposure" under Proposition 65.

The language of section 25501 was not haphazardly assembled, it was "carefully selected and tailored to clearly describe the scope of the exemption so as to implement [Proposition 65] in a reasonable manner." FSR at 6.

OEHHA's Discussion Draft would result in the *unreasonable* implementation of Proposition 65 and would directly contravene the clearly expressed intent noted in the Final Statement of Reasons.

OEHHA should not narrow the current naturally occurring regulation by introducing either the concept of extraction or of concentration as causing a naturally occurring chemical to no longer be protected by section 25501. The reasons why OEHHA should not narrow the naturally occurring regulation include at least the following:

- 1) Changing section 25501 to treat concentrated or extracted natural foods as exposures would be directly contrary to the words and intent of the original regulation;
- 2) OEHHA has offered no public health reason why the Discussion Draft is necessary or advantageous;
- 3) Adopting the Discussion Draft would significantly increase litigation targeting popular foods that are widely regarded as safe and increase overwarning; and,
- 4) Adopting the Discussion Draft would risk adverse trade actions, to the detriment of California and U.S. farmers and food producers.

I. The Discussion Draft's Change to Section 25501 Directly Contradicts the Words and Intent of the Original Regulation.

When section 25501 was adopted in 1989,¹ as now, the definition of “food” included both whole foods and food ingredients. See Cal. Health & Safety Code § 109935; 21 U.S.C. § 321(f)(3). By not adopting a separate definition of “food”, the Proposition 65 regulations effectively adopted the well accepted and established definition of food under existing California and federal law, which treats food ingredients as food. See *Arnett v. Dal Cielo* (1996) 14 Cal. 4th 4, 19-24; Cal. Civ. Code § 13.

The practical impact of OEHHA’s Discussion Draft would be to require warnings or threaten litigation for natural chemicals in many foods. Indeed, the Discussion Draft would nearly or wholly eliminate naturally occurring juices and food ingredients from the protection of section 25501. This would be contrary to the current language of section 25501 and to the intent that led to the current language.

When adopting section 25501, the Agency explained it as:

“reasonable and appropriate to implement the Act so that warnings are not required for naturally occurring chemicals in food.

[¶] Absence of such an exemption could unnecessarily reduce the availability of certain foods or could lead to unnecessary warnings, which could distract the public from other important warnings on consumer products.”

FSR at 4.

One comment during the process to adopt section 25501 requested a clarification that the human activity of “addition of a food containing a naturally occurring chemical to another food does not constitute an ‘exposure.’” FSR at 9. The Agency explained that such a clarification was not necessary:

“This amendment is not necessary because it is evident from the regulation as a whole that once a chemical is exempt as a naturally occurring chemical in food, the exempt status *of that particular chemical* will ‘carry over’ to any other food to which it is added.”

FSR at 9 (emphasis added).

One could not have clearer evidence of the Agency’s intent to exempt from the definition of exposure human actions that move a flavor ingredient or set of flavor ingredients from one food to another, so long as the flavor itself is a food.

¹ When adopted, section 25501 appeared in 22 C.C.R. § 12501. OEHHA moved the regulation without changing any text. For simplicity, all references here are to section 25501.

When upholding the validity of section 25501, the Court of Appeal came to the same conclusion. It described section 25501 as “a regulation to exempt from the warning requirement all naturally occurring chemicals in food products.” *Nicolle-Wagner v. Deukmejian* (1991) 230 Cal. App. 3d 652, 655-656. The Court of Appeal concluded “we are persuaded, on balance, that . . . the electorate did not intend naturally occurring substances to be controlled by Proposition 65.” *Id.* at 660.

II. OEHHA Has Offered No Public Health Justification for the Discussion Draft

OEHHA announced its Discussion Draft on July 22. None of the materials released by OEHHA in connection with the Discussion Draft offered any public health reason to justify the change under discussion. Indeed, no reason was offered at all for the Discussion Draft other than “clarification”. No explanation of why the change identified in the Discussion Draft is necessary or advantageous has been provided.

Likewise, OEHHA offered no public health justification for the Discussion Draft at the July 30 Workshop. There is no “problem” in the implementation of Proposition 65 that warrants consideration of the Discussion Draft. Absent a significant public health issue, there is no reason to disrupt a well-working aspect of Proposition 65.

III. Amending Section 25501 as Described in the Discussion Draft Would Significantly Increase Litigation Targeting Popular Foods Widely Regarded as Safe and Increase Overwarning

The application of section 25501(a) to food constituents that are themselves foods, as opposed to contaminants, has resulted in a reasonable approach to determining when foods should and should not have Proposition 65 warnings. Hundreds of thousands of food-related businesses have evaluated their products with respect to Proposition 65 and have navigated the current regulations concerning when a warning is, and is not, required.

When adopting section 25501, the Health & Welfare Agency noted that “natural” has a commonly understood meaning – “present in or produced by nature; not artificial or man-made.” FSR at 7. Thus, the existing section 25501 properly treats all foods, which includes food components that themselves are foods, as not creating an exposure covered by Proposition 65. Thus, a chemical “produced by nature” is excluded from the definition of exposure, whereas chemicals produced by human activity, pursuant to section 25501(a)(3) are considered exposures under Proposition 65.

In contrast to the long-standing language of section 25501, OEHHA’s Discussion Draft would treat as no longer “natural” many healthy foods produced in nature. OEHHA’s Discussion Draft contains the following new language:

“A listed chemical which has been extracted or concentrated from any source, such as a plant, may be present in a product as the result of human activity

even if the extraction or concentration did not change the Chemical Abstract Services Registry Number.”

This language would introduce significant litigation exposure to the growers, packers, handlers, processors and distributors of foods that are processed in ways that could be described as concentrating or extracting their naturally occurring chemical properties. Activities under this definition that could be characterized as concentrating or extracting a naturally occurring chemical include actions that remove water (drying, dehydrating, freeze-drying, evaporating, juicing); processes that separate (pressing, expelling, defatting); methods that reduce original sizing (milling or grinding); thermal processing (roasting); and the removal of portions of a product (hulling, shelling, sifting).

Indeed, the Discussion Draft would likely eliminate from the regulation’s intended protection a broad range of common and healthy foods and ingredients that are grown, processed and consumed in California. Products like rice and olive oil that go through a milling process might be impacted by the Discussion Draft. Juices and popular flavors such as almond extract, mint extract and citrus oils could be alleged to be “extractions”, making them litigation targets. Indeed, whenever a fruit or vegetable is no longer in its full, original state, one may expect Proposition 65 plaintiffs to target natural foods that use a portion of the whole food, arguing that using a portion is “extraction”, for many common, natural foods. For example, food made from beef, berries, carrots, celery, cilantro, citrus, cocoa, coconut, coffee, corn, ginger, grapes, licorice, milk, mint, nuts, peas, rice, rosemary, spices, spinach, tea, and tomatoes could suddenly face litigation exposure if the Discussion Draft were to be adopted.

Moreover, any notion that use of the word “may” in the Discussion Draft would limit or temper the reach of litigation is misplaced. Describing extraction and concentration as human activity almost certainly will lead to private enforcers taking the position in litigation that any and all extraction and concentration places natural food ingredients outside what section 25501 treats as “naturally occurring.” Because the burden of proving that a chemical is “naturally occurring” under section 25501 falls on the business, and because Proposition 65’s “bounty hunter” provisions incentivize over-enforcement of the law untethered to broader policy goals, the change envisioned by the discussion draft would increase the costs and risks of litigation for food companies and undermine the goals of section 25501.

As stated in section I, the Agency recognized decades ago that the absence of a naturally occurring exemption could unnecessarily reduce the availability of certain foods and generate unnecessary warnings that distract the public from other important warnings on consumer products. Unfortunately, the Discussion Draft would produce both results.

Because many packaged foods contain at least one input that has been dried, milled, pressed, juiced, or roasted, the exemption would become unavailable, or at a minimum uncertain, for a substantial share of the food supply. We recognize that the loss of the exemption does not unilaterally require a warning. However, for the chemicals principally at issue, the naturally occurring exemption as currently written has provided much clearer guidance. Changing this definition and basing the determination on how a food was processed would place warnings on many food products, including minimally processed products. This will confuse consumers about the actual safety and nutritional value of these foods.

IV. Amending the Regulation as Described in the Discussion Draft Would Risk Adverse Trade Actions by Important Export Markets

The expansion of what is considered a Proposition 65 “exposure” to include natural food ingredients and juices also creates very real negative international trade consequences – both for California farmers and for U.S. food and agricultural producers across the U.S.

Trading partners are increasingly seeking justification for imposing non-tariff barriers on U.S. products. Historically, Proposition 65 issues have sometimes created export barriers for California crops. These technical non-tariff barriers to trade (TBT) and sanitary and phytosanitary (SPS) barriers increasingly limit the number of products that California farmers can ship around the globe. This dynamic is partly driven by new federal trade policy ambitions, which utilize the imposition of tariffs on others and seek agreements with other nations under imposed economic duress. While U.S. tariffs on other countries provide disproportionate leverage (because of the size of the U.S. market) one of the few tools that smaller economies can use against the U.S. are TBT or SPS bans on the import of U.S. products. Import bans and limits are even more effective than tariffs as they represent an absolute and insurmountable barrier to trade. Examples of these practices are numerous and pre-date current trade wars.

Two recent examples of nontariff barriers harming U.S. agriculture are false claims of lead in apples asserted by Indonesia, and a European Union (EU) over-reaction to aflatoxin in nuts arriving from the U.S. Indonesian authorities in 2024 relied upon a false and never publicly available detection of lead in processed applesauce as justification for a ban on importation – not on sauce – but on fresh apples from U.S. orchards. The U.S. filed numerous objections and direct appeals to the Indonesian government. Rather than work collaboratively with the U.S., the nation instead decided to pursue de-listing U.S. apples under the nation’s Fresh Food of Plant Origin (FFPO) process – placing a veritable block on all U.S. apple producers. This case took a year to resolve, was widely documented, and U.S. farmers lost millions of dollars in revenue during the delay in market access.

Likewise, despite risk assessment to the contrary, restrictive limits for aflatoxin in several countries do not take into consideration naturally occurring levels, crop production conditions and statistical variability. Detections of have resulted in multiple barriers to trade erected in multiple EU member states. These EU member states have rejected consignments, and in some cases destroyed shipments of nuts without taking into consideration risk assessments, background levels, or scientific data. The U.S. estimated that this episode resulted in losses of hundreds of millions of dollars for U.S. farmers, resulting from strict application of limits and an inconsistent system of implementation across ports of entry within the EU.

The examples above show how trading partners are willing to use small, inconclusive or outright spurious issues as justification for restricting U.S. market access. Proposition 65 warnings on natural food ingredients or Proposition 65 litigation against natural food ingredients could well be used by trading partners to justify nontariff barriers.

Current tensions in international trade are not of California's making. Nevertheless, expansion of Prop 65 warnings and litigation into natural food ingredients could well exacerbate and inflame the international trade environment.

Conclusion

For the reasons described above, the organizations noted below request that OEHHA not proceed with any changes to section 25501(a)(3) and that OEHHA so announce its decision not to amend that subsection.



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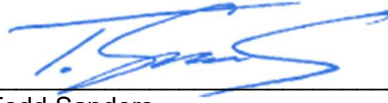


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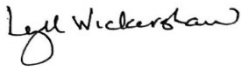
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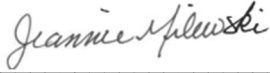
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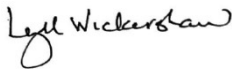
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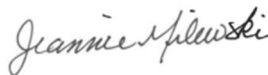
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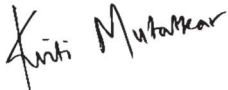
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